

Applicant: Jean-Claude Bystryn
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REMARKS

This responds to the Office Action dated September 6, 2006. In the Office Action, the Examiner rejected claims 1, 2, and 4, all of the claims pending in the application. Applicant respectfully requests reconsideration and reexamination in view of the following remarks.

The Examiner has rejected claims 1-2 and 4 under 35 U.S.C. § 103 (a), asserting that the claimed invention would have been obvious to a person of ordinary skill given the disclosures of Albino (1981) and Gupta (1984), and now in view of Bystryn (1986) and Gupta (1995), for the reasons stated in the previous Office Action. Briefly, in the prior Office Action, the Examiner asserts that Albino teaches the characterization of multiple melanoma associated surface antigens derived from multiple, different cell lines. The Examiner notes that although Albino does not teach culturing multiple different melanoma cell lines in a serum free media, Gupta teaches the purification of melanoma associated surface antigens from "spent" serum free media. The Examiner asserts that it would have been obvious to one of skill in the art at the time the invention was made to manufacture a polyvalent melanoma vaccine comprising multiple melanoma associated surface antigens derived from multiple cell lines cultured in serum free medium.

The Examiner further asserts that a person of ordinary skill in the art would have been motivated to do so because Albino taught that melanoma cell lines produce a diversity of surface antigens; Gupta taught that melanoma surface antigens are released from the surface of the melanoma cells, and that these antigens could be purified in media

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free of serum proteins. The Examiner further contends that one of skill in the art would have been motivated to combine the references because the use of serum free media provided a means to isolate a relatively purified population of melanoma associated surface antigens without contamination from serum proteins found in the culturing media containing serum. The Examiner also asserts that the use of multiple melanoma cell lines, as taught by Albino provides for diversity of melanoma antigens for which to generate a more diverse immune response. The Examiner concludes that one of ordinary skill would have a reasonable expectation of success in doing so because Gupta taught that the purification of melanoma surface antigens from serum free media would provide for an enriched population of surface antigens that was immunogenic.

Applicant respectfully requests reconsideration of the foregoing obviousness rejection. Applicant submits that the cited references, whether taken singly or in combination, do not render the claimed invention obvious. The newly cited Bystryn reference from 1986 relates to the work of the same research group, and would not be prior art to the earliest effective date of this application under 35 U.S.C. § 102(a). Likewise, the 1995 Gupta reference cannot properly be cited against the present application, as it was published long after the effective filing date hereof. Further, neither of the previously cited Gupta nor Albino references appears directed to treatment of melanoma; rather Gupta discusses development of a radioimmunoassay from tumor associated antigen isolated from spent culture medium of a single human melanoma cell line. The article appears to make no mention of use of the antigens as a vaccine, much less how to make and use such a vaccine. Moreover, since Gupta is working with only one cell line, there is no way the Gupta article can be stretched to relate to the claimed vaccine, which involves

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antigens pooled from multiple different cell lines. Albino discusses antigens taken from multiple cell lines from different metastases from the same patient, but again Albino seems interested primarily in studying the morphology of these different antigens, and in making comparisons of the similarities and differences of the antigens taken from these different metastases within the same patient. He reports on phenotypic differences among the different cell lines, such as growth rate, morphology, pigmentation, and the expression of surface antigens and glycoproteins. Albino likewise makes no mention of the possible use of the antigens that he obtained as a vaccine for the treatment of melanoma, nor does he appear to combine the antigens from the various cell lines to see if that act increases or decreases immune response.

There is simply no basis in the absence of hindsight for extrapolating from these references the invention claimed herein. Thus, it appears that the Examiner has taken two references involving melanoma antigens, and used the hindsight provided by the instant application to combine the references and fill in the considerable gaps in their respective discussions of melanoma. In the absence of hindsight, there would be no motivation to combine a reference discussing the morphology of several melanoma cell lines with a reference reporting on the design of a radioimmunoassay based upon antigens taken from a single melanoma cell line. Moreover, even if those references were combined, they would yield no clue concerning how to make or use a melanoma vaccine, or even that the antigens can be used in this way. Indeed, the references say so little about the immune response provoked by these antigens, that it cannot fairly said they even address the problem of how to treat melanoma, much less how to construct a usable vaccine for treating the disease. As such, applicant submits that the

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subject obviousness rejection is misplaced, and should be reconsidered and withdrawn.

The Examiner responds that he has carefully considered the foregoing response, but finds it unpersuasive, since the claims are directed to a composition, as opposed to a method of using a composition for the treatment of melanoma. Thus, the Examiner asserts, adding a preamble relating to a newly discovered use does not render claims to the composition, even with the added preamble, patentable.

Applicant maintains that he has isolated and purified a composition comprising pooled antigens shed from melanoma cell lines that have been cultured in serum free media that can be safely used as a vaccine for treating melanoma, and that his claims define an invention patentable over the cited references, and that he claims a vaccine composition including the immunogenic composition obtained from pooling tumor associated antigens shed by several melanoma cell lines in a diluent such a normal saline, and an adjuvant. The cited references do not recite pooled cell free antigens in a pharmaceutically effective vehicle. Neither reference refers to a vaccine, and neither provides any motivation to attempt to use the antigens discussed therein as a vaccine. In view of the gulf between the disclosures of the cited references and the claimed invention, the present obviousness rejection cannot stand.

In sum, applicant submits that the claims as amended overcome the foregoing obviousness rejection, and respectfully requests that the rejection be reconsidered and withdrawn. Notice of allowability of the pending claims is respectfully requested.

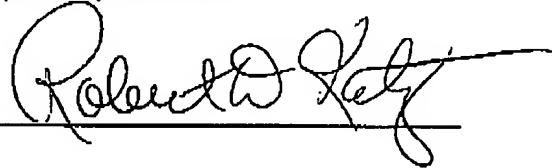
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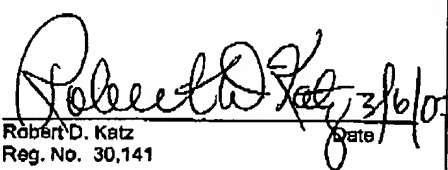
The Commissioner is hereby authorized to charge any fee related to the filing of this response to deposit account no. 03-3125. In addition, if any further extension is required to file or consider this response, applicant hereby requests such extension, and authorizes the fee therefor to be charged to the foregoing deposit account.

Respectfully submitted,

Dated: March 6, 2007

By:



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| I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office (571) 273-8300 on the date set forth below. | |
|  | 3/6/07 |
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